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MAY 30 2008

510(k) SUMMARY

Owner/Operator:

W. L. Gore & Associates, Inc
555 Paper Mill Road
Newark, Delaware 19711 USA
Owner/Operator #: 9925013

Submission Contacts:

Michael J. Titus
Regulatory Affairs Associate
W.L. Gore & Associates, Inc.
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Elkton, Maryland 21922 USA
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Submission Date:

April 14, 2008

Device Name:

Proprietary Name: GORE INFINIT Mesh
Common Name: INFINIT Mesh
Classification Name: Surgical Mesh
Product Code: FTL
Class: II

Substantial Equivalence:

Predicate devices

1. **Product Name:** GORE DUALMESH® Biomaterial
   510k #: K992189
   Manufacturer: W.L. Gore & Associates, Inc.

2. **Product Name:** Prolene™ Soft (Polypropylene) Mesh
510k #: K001122
Manufacturer: ETHICON, Inc.

The GORE INFINIT Mesh is comprised of the same base material (PTFE) as the predicate device, GORE DUALMESH® Biomaterial, and has the same intended use. The GORE INFINIT Mesh is different from the other predicate device, the PROLENE™ Soft Mesh, in that the PROLENE™ Soft Mesh device is made of polypropylene. The GORE INFINIT Mesh also has the same general intended use as the PROLENE™ Soft Mesh. Differences between the devices do not raise any significant issues of safety or effectiveness.

Intended Use:

GORE INFINIT Mesh is indicated for use in the reconstruction of hernias and other soft tissue deficiencies.

Device Description

GORE INFINIT Mesh is a flat nonabsorbable surgical mesh constructed from monofilament expanded polytetrafluorethylene (PTFE) fibers. The fibers are warp knitted into a textile pattern with bi-axial stretch that allows the material to comply with native tissue. The warp knit pattern also allows the mesh to be custom tailored without unraveling of the edges. The mesh is knitted with a pore size that allows appropriate tissue integration without negatively affecting abdominal wall compliance.

Materials

GORE INFINIT Mesh is made from expanded polytetrafluorethylene (PTFE) fibers. This material is the same as that used in the predicate device, GORE DUALMESH® Biomaterial, and has a significant history of safe and efficacious use as implantable material. There are no other materials in the implanted device.

W. L. Gore & Associates, Inc.
GORE INFINIT Mesh
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Performance

The GORE INFINIT Mesh device has performance characteristics comparable to the PROLENE™ Soft Mesh predicate device based on bench testing and in accordance with those characteristics specified in the "Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh". Nonclinical laboratory (animal) testing and clinical performance data were not evaluated as part of this application.

Conclusions

Based on the information provided herein, we conclude that the GORE INFINIT Mesh device is substantially equivalent to its predicates in terms of design, intended use, principle of operation and performance attributes.

Difference between the predicates and the GORE INFINIT Mesh do not raise any significant issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 30 2008

W.L. Gore & Associates, Inc.
% Mr. Michael J. Titus
Regulatory Affairs Associate
301 Airport Road
Elkton, Maryland 21922-1408

Re: K081069
Trade/Device Name: GORE INFINIT Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: April 14, 2008
Received: April 15, 2008

Dear Mr. Titus:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081069

Device Name: GORE INFINIT Mesh

Indications For Use:

GORE INFINIT Mesh is indicated for use in the reconstruction of hernias and other soft tissue deficiencies.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

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